

Claims:

We claim:

1. A stable, aqueous pharmaceutical formulation comprising an immunoglobulin, a phosphate buffer, a polysorbate, and sodium chloride.
2. The formulation of claim 1, wherein the polysorbate is polysorbate 80.
3. The formulation of claim 2, wherein the polysorbate 80 is present in an amount of about 0.001% to about 2.0% (w/v).
4. The formulation of claim 3, wherein the polysorbate 80 is present in the amount of about 0.02% (w/v).
5. The formulation of claim 1, wherein the immunoglobulin is present in the amount of about 0.1 mg/mL to about 200 mg/mL.
6. The formulation of claim 5, wherein the immunoglobulin is present in the amount of about 1.7 mg/mL.
7. The formulation of claim 5, wherein the immunoglobulin is present in the amount of about 5 mg/mL.
8. The formulation of claim 5, wherein the immunoglobulin is present in the amount of about 20 mg/mL.
9. The formulation of claims 1, wherein the formulation has a pH of about 3.0 to about 7.0.
10. The formulation of claim 9, wherein the pH is about 5.5 to about 6.5.
11. The formulation of claim 10, wherein the pH is about 6.0 ± 0.5 .

12. The formulation of claim 1, wherein the formulation is in a fixed volume and the immunoglobulin is present in the amount of about 50 mg/mL.
13. The formulation of claim 12, wherein the immunoglobulin binds alpha-4 integrin.
14. The formulation of claim 13, wherein the immunoglobulin is natalizumab.
15. The formulation of claim 1, wherein the phosphate buffer is at pH 6.0 ± 0.5 , the polysorbate is polysorbate 80 and is present in an amount of about 0.02% (w/v), the immunoglobulin is natalizumab, and wherein the formulation is stable at a temperature of about 2°C to about 8°C for at least 6 months.
16. The formulation of claim 15, wherein natalizumab is present in an amount of about 20 mg/mL to about 150 mg/mL.
17. The formulation of claim 1, wherein the formulation is isotonic.
18. The formulation of claim 1, wherein the immunoglobulin is a monoclonal antibody.
19. The formulation of claim 18, wherein the monoclonal antibody is natalizumab.
20. The formulation of claim 19, wherein the antibody is present in an amount of about 0.1 mg/mL to about 200 mg/mL.
21. The formulation of claim 19, wherein the antibody is present in an amount of about 1 mg/mL to about 150 mg/mL.
22. The formulation of claim 21, wherein the antibody is present in an amount of about 1.7 mg/mL or about 50 mg/mL.

23. The formulation of claim 18, wherein the antibody is present in the amount of about 15 mg/mL to about 50 mg/mL.

24. The formulation of claim 18, wherein the antibody is present in the amount of about 20 mg/mL.

25. The formulation of claim 1, wherein the formulation further comprises histidine.

26. The formulation of claim 25, wherein the polysorbate is polysorbate 80.

27. A method of treating a patient with variable weight for a condition with a therapeutic amount of an immunoglobulin comprising administering a formulation of claim 1 to said patient wherein the condition is treated by administration of the formulation.

28. The method of claim 27, wherein the immunoglobulin is natalizumab.

29. A composition comprising a sodium phosphate, a polysorbate, a protein and NaCl with a pH of 6.0 ± 0.5 , wherein the composition is stable when stored at about 5 °C to about 8 °C for greater than 6 months.

30. The composition of claim 29, wherein the polysorbate is polysorbate 80 and is present in an amount of about 0.001% to about 2.0% (w/v).

31. The composition of claim 29, wherein the protein is an immunoglobulin which is present in an amount of about 0.01 mg/mL to about 200 mg/mL.

32. The composition of claim 29, wherein the polysorbate is polysorbate 80 and is present in the amount of about 0.02% (w/v), the NaCl is present in the amount of 150 mM, the phosphate buffer is present in the amount of 10 mM, and the immunoglobulin is natalizumab and is present in the amount of 1.7 mg/mL, 5 mg/mL, 20 mg/mL or 50 mg/mL.

33. A method of preparing a stable protein containing formulation comprising admixing sodium phosphate, sodium chloride, a polysorbate and a protein and adjusting the pH of the mixture with phosphoric acid to about pH 6.0 ± 0.5 .

34. The method of preparing a stable protein containing formulation of claim 33, wherein the sodium phosphate is present in an amount of about 10 mM, the sodium chloride is present in an amount of about 150 mM, the polysorbate is polysorbate 80 and is present in an amount of about 0.02% (w/v) and the protein is natalizumab.

35. The method of preparing a stable protein containing formulation of claim 33, wherein natalizumab is present in an amount of about 20 mg/mL to about 200 mg/mL.

36. The method of preparing a stable protein containing formulation of claim 35, wherein natalizumab is present in an amount of about 150 mg/mL.

37. The method of preparing a stable protein containing formulation of claim 33, wherein the protein is lyophilized in the formulation of claim 1.

38. The method of preparing a stable protein containing formulation of claim 37, wherein the polysorbate is polysorbate 80 and is present in an amount of about 0.02% (w/v) and the protein is natalizumab.

39. The method of preparing a stable protein containing formulation of claim 37, wherein the formulation further comprises histidine.

40. The method of preparing a stable protein containing formulation of claim 33, wherein the protein is lyophilized in a solution comprising 5 mM histidine, 20 mg/mL sucrose and 0.02% polysorbate 80 at a pH 6, and wherein the protein is natalizumab at a concentration of 20 mg/mL.

41. An article of manufacture comprising a container holding the stable formulation of claim 1.

42. A method for treating a patient with variable weight for a condition, comprising simultaneously or sequentially administering to the patient a therapeutically effective combination of a formulation of claim 1 and a compound or therapy effective against the condition.